REMARKS

Claims 1-18, 20, 21, 23, 24 and 33-55 are pending in the application and are the subject of the instant office action. Claims 13-18 have been indicated by the Examiner to contain allowable subject matter.

Claims 1, 11, 12, 33, 42, and 47 were objected to in the office action as referencing an inappropriate SEQ ID NO. In particular, the Examiner has noted that SEQ ID NO:1 in the application's Sequence Listing provides a nucleic acid sequence while the subject claims refer to an amino acid sequence. These claims have been amended, as shown herein, to correctly refer to the amino acid sequence of SEQ ID NO:2 of the Sequence Listing filed for the present application. In the Response to Notice to Comply filed by Applicants on June 14, 2000, Applicants amended the specification accordingly to correct this inadvertent error. It is believed that these amendments are fully supported by the application and do not introduce new matter.

For the Examiner's convenience, a clean copy of the (amended) paragraphs in the specification and now pending claims 1-18, 20, 21, 23, 24, and 33-55 is provided above. The amendments are illustrated in the attached pages entitled "Marked Up Version To Show Changes Made".

Formal Drawings

In response to the notice of informalities in the drawings (PTO Form 948), Applicants are filing herewith formal drawings (16 sheets) for the present application. The Brief Description of the Drawings on pages 7 and 8 of the specification has been amended, as shown herein, to reflect the numbering of the formal drawings.

Section 102 and 103 Rejections

Claims 1-4, 8-9, 20-21, 23-24, 33-34, 38, 42-43, 47-48 and 52 were rejected under Section 102(e) as being anticipated by Ni et al. Claims 5-7, 10, 35-37, 39-41, 44-46, 49-51 and 53-55 were rejected under Section 103(a) as being obvious over Ni et al., in view of Gussow wt al., Janeway

et al., and Pan et al.

In addition the following rejections were maintained:

Claims 1-5, 9, 10, 21, 23, 24, 33, 34, 38-40, 42, 43, 47, 48 and 52-54 were rejected as being obvious over Pan et al. in view of Campbell;

Claims 1-10, 20, 21, 23, 24, 33, 34, 36-43, 45-48 and 50-55 were rejected as being obvious over Pan et al. in view of Campbell and Gussow et al.;

Claims 35, 44 and 49 were rejected as being obvious over Pan et al. in view of Campbell and further in view of Janeway et al.

As stated in Applicants' previous response, the Campbell, Gussow et al., and Janeway et al. references may relate to certain aspects of techniques for making monoclonals or human or chimeric antibodies (in a generic manner), but none of these references fill the void left by the Pan et al. reference and likewise do not fill the void left by Ni et al.

It is Applicants' position that neither Ni et al. nor Pan et al. provide enabling disclosures for the claimed anti-DR4 antibodies, in particular the classes or species of DR4 antibodies as claimed in claim 33 (i.e., an agonist antibody having apoptotic activity in a cancer cell(s)), claim 42 (i.e., a blocking antibody which blocks binding of Apo-2 ligand to DR4), or claim 47 (i.e., a blocking antibody that blocks binding of Apo-2 ligand induced apoptosis in a cancer cell(s)) would not be expected.

In the office action, the Examiner asserts that it would be obvious to one of ordinary skill to make antibodies to the extracellular portion of DR4 (including agonist and blocking antibodies). **This position articulated by Examiner Decloux appears to be completely opposite to the position asserted by the Group 1646 Examiner in the prosecution of the Ni et al.'s DR4 antibody claims.** The undersigned respectfully submits that the present Applicants should not be unduly prejudiced by inconsistent standards being applied by different Groups within the Patent Office.

To better illustrate this inconsistency, the undersigned has attached for the Examiner's convenience a copy of the office action dated November 26, 2001 from the publicly available file history of Ni et al.'s

US Patent 6,461,823[1] issued October 8, 2002, which is a divisional of Ni et al., US Patent 6,342,363. In that attached office action at pages 4-5, that Examiner asserts that agonist or antagonist antibodies to DR4 are not enabled by the disclosure of Ni et al., and she states, among other things,:

> Making an antibody that inhibits or stimulates the activity of the protein to which it binds is unpredictable and complex even if the regions of activity in the protein are known...

This attached office action document clearly reveals that claims to DR4 antibodies by Ni et al. and in the present application are being examined under two completely different and opposite standards. The file history of Ni et al., US Patent 6,461,823, suggests that the Patent Office believes the disclosure of Ni et al. to be non-enabling for agonist and antagonist antibodies to DR4, and yet in the instant application, the Ni et al. disclosure is being cited and applied as Section 102(e) art against Applicants' claims to such functional classes of DR4 antibodies.

In view of these prejudicial circumstances, the undersigned respectfully believes that fairness dictates the following actions be taken by the patent office:

* that the final rejection of the instant claims be withdrawn;

* that all Examiners at the Patent Office charged with the responsiblity of examining any party's patent claims directed to DR4 and DR4 antibodies adopt and apply consistent standards; and

---

[1]Applicants cited this patent reference to the Examiner in a Supplemental Information Disclosure Statement filed on October 25, 2002 in the present application.

* that the present claims be examined once again in accordance with those consistent standards.

Respectfully submitted,
GENENTECH, INC.

Dated: March 5, 2003 By: Diane L. Marschang

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MARKED UP VERSION TO SHOW CHANGES MADE

IN THE SPECIFICATION:

In the paragraphs on page 7, lines 24-31, the text has been amended as follows:

----Figures 1A-1B show[s] the nucleotide sequence (SEQ ID NO:1) of a cDNA for human DR4 and its derived amino acid sequence (SEQ ID NO:2). The respective nucleotide and amino acid sequences for human DR4 are also reported in Pan et al., Science, 276:111 (1997).

Figures 2A-2B show[s] the FACS analysis of two anti-DR4 antibodies, 4E7.24.3 ("4E7") and 4H6.17.8 ("4H6") (illustrated by the bold lines) as compared to IgG controls (dotted lines). Both antibodies recognized the DR4 receptor expressed in human 9D cells. –

In the paragraph on page 8, lines 1-4, the text has been amended as follows:

–Figures 6A-6B [is a] are graphs showing results of an ELISA testing binding of DR4 antibodies, 4E7.24.3 and 4H6.17.8, to DR4 and to other known Apo-2L receptors referred to as Apo-2, DcR1, and DcR2.---

In the paragraph on page 8, lines 15-17, the text has been amended as follows:

–Figures 9A-9B show[s] apoptotic activity of DR4 antibodies, 4H6, 4E7, 4G7, 4G10.20.6 ("4G10"), 3G1.17.2 ("3G1"), 5G11, 1H8.17.5 ("1H8"), and 1H5.24.9 ("1H5") on SKMES colon tumor cells in the presence of goat anti-mouse IgG Fc. ---

IN THE CLAIMS:

Please amend claim 1 as follows:

1. (Twice Amended) An isolated antibody which specifically binds to DR4 polypeptide comprising amino acid residues 24 to 218 of Figure 1 (SEQ ID NO:[1]2).

Please amend claim 11 as follows:

11. (Twice Amended) An isolated monoclonal antibody which specifically

binds to DR4 polypeptide comprising amino acid residues 24 to 218 of Figure 1 (SEQ ID NO:[1]2) and which has the same biological characteristics of (1) the monoclonal antibody produced by the hybridoma cell line deposited under American Type Culture Collection Accession Number ATCC HB-12695; (2) the monoclonal antibody produced by the hybridoma cell line deposited under American Type Culture Collection Accession Number ATCC HB-12694; or (3) the monoclonal antibody produced by the hybridoma cell line deposited under American Type Culture Collection Accession Number ATCC PTA-99.

Please amend claim 12 as follows:

12. (Twice Amended) An isolated monoclonal antibody which specifically binds to DR4 polypeptide comprising amino acid residues 24 to 218 of Figure 1 (SEQ ID NO:[1]2) and which binds to the same epitope as (1) the epitope to which the monoclonal antibody produced by the hybridoma cell line deposited under American Type Culture Collection Accession Number ATCC HB-12695 binds; (2) the epitope to which the monoclonal antibody produced by the hybridoma cell line deposited under the American Type Culture Collection Accession Number ATCC HB-12694 binds; or (3) the epitope to which the monoclonal antibody produced by the hybridoma cell line deposited under American Type Culture Collection Accession Number ATCC PTA-99 binds.

Please amend claim 33 as follows:

33. (Once Amended) An isolated antibody which binds to DR4 polypeptide comprising amino acid residues 24 to 218 of Figure 1 (SEQ ID NO:[1]2) and which induces apoptosis in at least one type of mammalian cancer cell.

Please amend claim 42 as follows:

42. (Once Amended) An isolated antibody which binds to DR4 polypeptide comprising amino acid residues 24 to 218 of Figure 1 (SEQ ID NO:[1]2) and which blocks binding of Apo-2 ligand to said DR4 polypeptide.

Please amend claim 47 as follows:

47. (Once Amended) An isolated antibody which binds to DR4 polypeptide

comprising amino acid residues 24 to 218 of Figure 1 (SEQ ID NO:[1]2) and which blocks Apo-2 ligand induced apoptosis in at least one type of mammalian cancer cell.

From File History of Ni et al., US Patent 6,461,823

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/448,868	11/24/1999	JIAN NI	1488.1300004	5546

7590 11/26/2001

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EXAMINER	
KAUFMAN, CLAIRE M	

ART UNIT	PAPER NUMBER
1646	15

DATE MAILED: 11/26/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/448,868	NI ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 1999 and 06 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-83* is/are pending in the application.

4a) Of the above claim(s) *23,25-35,43,45,47-57,65,74 and 83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *22,24,36-42,44,46,58-64,66-73 and 75-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *22-83* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 November 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .

DETAILED ACTION

The amendments filed 11/24/99 and 4/30/01 have been entered.

Election/Restrictions

Upon reconsideration of the restriction requirement of 7/6/01 (paper #12), it was concluded that it should have been a species election with the full-length protein being the generic claim.

During a telephone conversation with Elizabeth J. Haanes on 11/5/01 a provisional election was made with traverse to prosecute the invention of Group I drawn to an antibody to the polypeptide comprising amino acids 1-468 of SEQ ID NO:2 with a species election of antibody to the polypeptide comprising amino acids 24-238 (the extracellular domain) of SEQ ID NO:2, claims 22, 24, 36-42, 44, 46, 58-64, 66-73 and 75-82. Affirmation of this election must be made by applicant in replying to this Office action. Claims 23, 25-35, 43, 45, 47-57, 65, 74 and 83 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant's election with traverse of 9/6/01 in Paper No. 14 is acknowledged. As the traversal relates to the new species election, it will be addressed here. The traversal is on the ground(s) that 1) since there is extensively overlapping scope of all antibodies claimed including with an antibody to the full-length protein, all claimed antibodies should be examined; 2) no showing of serious search burden has been set forth and the search scope would be coextensive with all claimed antibodies; and 3) the antibodies claimed are members of a Markush group and are sufficiently few in number or so closely related that examination of the entire claim can be made without serious burden. This is not found persuasive because:

With respect to point (a) above, the Examiner explained why the multitude of claimed antibodies presents a serious search burden in the presentation of the requirement in paper #12, 2nd paragraph of p. 3. Further, even though an antibody to a fragment of SEQ ID NO:2 could anticipate an antibody to full-length SEQ ID NO:2, an antibody to one fragment would not necessarily anticipate an antibody to another fragment if the antibody binding region is not shared by the two fragments. As previous discussed for "word" searches, this kind of "word" or

"oligo" search only produces a certain number of saved "hits" in the USPTO sequence search computers. Each fragment must be searched and a separate "oligo" search must be performed within each fragment. For these reasons, examining all claimed antibodies would present a serious search burden.

With respect to 2) above, see the paragraph immediately above for a discussion of search burden. While examination would be coextensive in that fragments with overlapping identical protein regions might present the same antibody art, not all regions of all fragments overlap. For the reasons discussed above, each fragment requires its own search.

With respect to point 3) above, it is noted that at the time restriction, the claims were not in Markush format. While the examiner listed the different inventions in Markush format, that was to simplify the listing of the numerous inventions (now considered species of the full-length). In this case, the different antibodies are not sufficiently few in number or so closely related that a search and examination of the entire group can be made without serious burden. With respect to the search burden that this presents, see the discussion of point 1), above. Further aside from each fragment's structural relationship to the full-length protein, there is no substantial structural feature among the fragments, many of which do not overlap, disclosed as being essential to that utility. Such would seem impossible, as the claimed fragments are, in many cases, non-overlapping, and thus do not share *any* structural feature.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

Figures 2A and 2B are objected to as being duplicates of each other.

Claim Objections

Claims 24 and 46 are objected to for depending on non-elected claims. The claims should be amended to include only the elected invention. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39, 40, 61, 62, 70, 71, 79 and 80 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and the invention.

The claims are drawn to agonistic or antagonistic antibodies to DR4. Making an antibody that inhibits or stimulates the activity of the protein to which it binds is unpredictable and complex even if the regions of activity in the protein are known, which is not the case here. It was known at the time the invention was made that the ligand for DR4 is involved in causing apoptotic cell death and is called Fas/APO-2 (Example 5 of the specification). While it is expected that the Fas ligand binds DR4's extracellular domain, finding sites which allow a binding antibody to have inhibitory or stimulatory activity in the absence of structural information about the receptor besides its amino acid sequence and general domain structure would require undue experimentation without a reasonable expectation of success since so little is known about which amino acids or potential epitopes would be likely to be necessary for receptor activity.

Because of the lack of information in the prior art about antibodies to death domain-containing receptors (DDR), let alone anti-DDR antibodies that agonize or antagonize the receptor, the level of skill in the art is low. There is no guidance in the specification about what structural features would be necessary for an antibody not only to bind DR4 of SEQ ID NO:2 as claimed, but also to be an agonist or antagonist of the DR4 receptor; although, making a **generic** antibody is well within the skill of one in the art (e.g., claim 22). Making an antibody that stimulates or inhibits the activity of DR4 is unpredictable and complex even if the regions of activity of the ligand to which the antibody binds are known, which is not the case here. Because of the relatively low skill level in the art, lack of teachings in the specification and prior art about how the structure of the receptor is related to activation or inhibition of its receptor, lack of examples in the specification or prior art of anti-DDR antibodies and, more particularly, agonistic or antagonistic antibodies, the unpredictability of making an anti-ligand antibody which

is an agonistic or antagonist of the DR4 receptor, it would require undue experimentation to make the invention as claimed.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 24, 42, 44, 46, 64, 66, 73, 75, 82 and dependent claims 36-41, 58-63, 67-72 and 76-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 42, 64, 73 and 82 are indefinite because the method requires a specific antibody to be produced, but no specific immunogen is set forth. This rejection could be obviated by, for example, specifying that the immunogen is the protein consisting of the sequence of SEQ ID NO:2.

Claims 22, 24, 44, 46, 66 and 75 are indefinite because the metes and bounds of the claim cannot be determined. The use of the term "specifically binds" in not clear since the specification does not define the term and it is not clear in this instance whether this limits antibodies to those that bind only DR4 of SEQ ID NO:2, any mammalian DR4, any DDR, etc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35

Claims 22, 24, 36-42, 44, 46, 58-64, 66-73 and 75-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chinnaiyan et al. (Science, Nov. 1996) and Wiley et al. (US Patent No. 5,763,223) in view of Lerner et al. (Advances in Immunology, 1984) and Applicants' admission on page 27, lines 28-38.

Chinnaiyan et al. teach the DR3 polypeptide, a death domain-containing receptor (DDR), which has a sequence identical to the instant DR4 polypeptide of SEQ ID NO: 2 from amino acids 248-254, corresponding to amino acids 210-216 of DR3 the DcR3 polypeptide (see FIG 2A of the instant appliation). Also taught is an antibody that bind the Flag epitope tag (Fig. 3). The antibody was used for immunpreicptation to detect receptor-ligand association.

Wiley et al. teach conventional methods of making antibodies to TRAIL (a ligand for a death domain-containing receptor). Such methods include those for making monoclonal, polyclonal, antigen-binding fragments of and chimeric antibodies (col.20, line 59 through col. 21 line 24). Also taught are uses of antibodies including TRAIL detection and purification (col. 21, lines 25-28).

Lerner et al. teaches (p. 14, 7 lines from bottom) that "one can make site-specific antibodies to virtually any region of a protein...." Also taught is that antibodies can be made to denature protein fragments 6 amino acids long (p. 15, first paragraph).

Applicants admit (page 27, lines 28-38) that "it is well known in the art that relatively short synthetic peptides that mimic part of a protein sequence are routinely capable of eliciting antiserum that reacts with the partially mimicked protein.... Peptides capable of eliciting protein-reactive sera are frequently represented in the primary sequence of a protein, can be characterized by a set of simple chemical rules, and are confined neither to immunodominant regions of intact proteins (*i.e.*, immunogenic epitopes) nor to the amino carboxyl terminals.

It would have been obvious to one of skill in the art at the time the invention was made to produce antibodies to any fragments of the DR3 polypeptide taught by Chinnaiyan et al. using the conventional and routine methods disclosed by Wiley. This includes the fragment of DR3 that is identical to the disclosed DR4. Antibodies to the DDR DR3 fragments would have been desirable for DR3 detection and purification purposes as taught for TRAIL by Wiley. One reason for this is that detection with an antibody that directly binds the protein is more spatially

accurate than detection with an epitope tagging antibody. It also would have desirable as a tool to better understand DDR structure/function relationships. It would have been obvious to have the antibody in a composition with a pharmaceutically acceptable carrier such as a buffer so it is in a solution suitable for storage or use.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.

Patent Examiner, Art Unit 1646

November 16, 2001